DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JUL - 2 1998

James P. Thompson
Manager, Worldwide Regulatory Affairs
Dermik Laboratories, Inc.
500 Arcola Road, P.O. Box 1200
Collegeville, PA 19426-0107

RE: **NDA# 20-743**
Noritate (metronidazole cream) Cream, 1%
MACMIS ID # 6810

Dear Mr. Thompson:

This letter is in reference to Dermik Laboratories, Inc.'s (Dermik) February 2, 1998, submission under cover of FDA Form 2253 for Noritate (metronidazole cream) Cream, 1% to the Division of Drug Marketing, Advertising, and Communications' (DDMAC). As part of DDMAC's routine monitoring of prescription drug advertising, DDMAC has reviewed a visual aid for Noritate Cream identified as 0198001, and has determined that it is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Specifically, the bullet point "May enhance compliance" is misleading without adequate substantiation. In addition, the use of the headline "Compliance," is misleading in the absence of Noritate-specific compliance data that substantiate the claims. On two previous occasions DDMAC has notified Dermik that such claims would be misleading (See letters dated October 17, and November 25, 1997).

DDMAC requests that Dermik take the following actions:

1. Immediately discontinue the use of these and all other promotional materials for Noritate that contain the same or similar violations.

2. Provide to DDMAC, in writing, Dermik's intent to comply with #1 above. Your response should be received by July 14, 1998.

If Dermik has any questions or comments, please contact undersigned by facsimile (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to the MACMIS ID # 6810, in addition to the NDA number.

Sincerely,

/S/

Jean E. Raymond, P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications